EXHIBIT E

UpToDate Treatment Recommendations for Colovesical Fistula

Colovesical fistulas

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All topics are updated as new evidence becomes available and our peer review process is complete.

Literature review current through: Nov 2019. | **This topic last updated:** Jun 24, 2019.

INTRODUCTION

A colovesical fistula (CVF) is an abnormal connection between the colon and urinary bladder. Although they are uncommon, CVFs can cause significant morbidity, affect quality of life, and may lead to death, usually secondary to urosepsis [1,2]. Although a CVF can be diagnosed clinically, imaging and endoscopy are often required to delineate the extent of a fistula and to elucidate its etiology [3]. Surgery is usually required to repair a CVF.

The epidemiology, etiology, clinical features, diagnosis, and management of colovesical fistulas are reviewed here. Other types of fistulas related to the gastrointestinal and urological systems are covered in separate topic reviews. (See "Enterocutaneous and enteroatmospheric fistulas" and "Rectovaginal and anovaginal fistulas" and "Anorectal fistula: Clinical manifestations, diagnosis, and management principles" and "Urogenital tract fistulas in women".)

EPIDEMIOLOGY

The precise incidence of colovesical fistulas (CVFs) is unknown. It is estimated that CVFs account for 1 in every 3000 surgical hospital admissions [4]. In patients with diverticular disease, 2 to 18 percent were found to have CVFs [5-8]. In patients with Crohn's disease, less than 1 percent developed a CVF [9].

The male-to-female ratio of CVF is approximately 2 to 3:1 [1,10-13]. Females are protected possibly because the uterus and broad ligaments act as a barrier between the sigmoid colon and the bladder.

This theory is supported by the fact that a high percentage of females with CVFs (>50 percent in some series) have had a previous hysterectomy [13].

CVFs most commonly affect patients in their sixth or seventh decades. The mean age at presentation is between 55 and 75 years [1,10-12].

ETIOLOGY

Colovesical fistulas (CVFs) are most commonly a complication of diverticulitis, cancer, or Crohn's disease.

- Diverticulitis accounts for 65 to 79 percent of cases, with the sigmoid being the most frequently affected portion of the colon [2,5,11,14,15]. In these patients, a ruptured diverticulum leads to peridiverticular inflammation and abscess, which eventually erodes into the bladder.
- Cancer accounts for 10 to 20 percent of CVFs. Malignant CVFs usually result from direct invasion of a colonic adenocarcinoma into the urinary bladder [2]. Less often, the primary tumor may arise from the bladder, adnexa, or other pelvic organs [16,17].
- Longstanding Crohn's colitis is responsible for 5 to 7 percent of colovesical fistulas [2].

Other rare etiologies of CVF include complications from surgery or colonic stents [18], tuberculosis [19], lymphoma [20], spilled gallstones [21], chicken bone ingestion [22], appendicitis [23], coccidiomycosis [24], pelvic radiation therapy [25], and penetrating abdominal trauma [26].

CLINICAL MANIFESTATIONS

Although the underlying cause of colovesical fistulas (CVFs) most often originates in the colon, patients usually present with lower urinary tract symptoms including:

- Pneumaturia (in 50 to 95 percent of cases)
- Fecaluria (in 40 to 70 percent of cases)
- Suprapubic pain (in 30 to 90 percent of cases)
- Dysuria
- Urgency
- Frequency

- Gross hematuria (rare)

Pneumaturia is usually appreciated toward the end of urination because the collection of gas usually sits at the top of the bladder. Pneumaturia and/or fecaluria can be found in approximately 90 percent of patients with a CVF [2,3,13,27-29]. Other causes of pneumaturia, including recent instrumentation, urinary tract infections with gas-forming organisms, and emphysematous cystitis, are either simple to exclude or exceptionally rare [28]. Thus, the finding of pneumaturia or fecaluria is virtually pathognomonic for urinary tract fistulas, and patients presenting with this condition should be presumed to have a CVF and investigated accordingly.

In addition, some patients report passage of cloudy, malodorous urine, often with visible debris. Over time, the cystitis associated with a CVF may evolve to pyelonephritis, systemic infections, or renal impairment.

Beyond urinary tract symptoms, patients with CVF may note gastrointestinal symptoms attributable to underlying diverticulitis, colon cancer, or Crohn's disease. Uncommonly, they may report systemic symptoms such as fever, excessive sweating, or malaise. Some patients report urine passage per rectum, but this is rare. [13].

Aside from visible debris in the urine, findings on physical examination are nonspecific and often reflect the underlying etiology of the fistula. These can include abdominal tenderness, abdominal mass, weight loss, or cutaneous manifestations of Crohn's disease. (See "Perianal Crohn's disease".)

EVALUATION AND DIAGNOSIS

Colovesical fistulas (CVFs) should be suspected in patients who present with pneumaturia or fecaluria. The diagnosis is confirmed by abdominopelvic computed tomography (CT) scan with oral or rectal but not intravenous (IV) contrast demonstrating air or contrast material in the bladder with adjacent thickened colonic and vesicular walls. Patients who are diagnosed with a CVF should undergo colonoscopy to rule out an underlying malignancy. Patients who are suspected of having a malignant fistula (due to colon or bladder cancer) should also undergo a cystoscopy to assess possible cancer invasion of the bladder. Most other investigations are optional, case-specific, or reserved for low-resource settings.

Initial tests to diagnose colovesical fistula

Urinalysis and urine culture — Urine laboratory studies are invariably abnormal in colovesical fistulas. Routine urinalysis reveals pyuria and bacteriuria. Microscopic evaluation will show sediments of vegetable matter, leukocytes, and undigested muscle fibers (rhabdomyocytes) in keeping with fecaluria [30]. Urine cultures will usually grow enterococci or coliforms, mostly *Escherichia coli* (81

percent of cultures). Cultures often grow a single species (43 to 71 percent) rather than the expected mixed flora [25,30,31]. Other routine blood tests, such as serum creatinine and leukocyte count, are nonspecific [25].

Abdominopelvic CT with oral or rectal contrast — An abdominopelvic CT with oral or rectal contrast (but **not** IV contrast) is the imaging test of choice for diagnosing a CVF. Although the CVF tract is only visualized in approximately 64 percent of cases [12], CT is extremely sensitive for the presence of intravesical air and contrast. Considering this finding, some authors have reported that CT can accurately detect the presence of CVF in up to 90 to 100 percent of patients [2,32].

If a fistula is suspected, the initial images of the CT scan should be acquired with oral or rectal contrast, but **without** IV contrast. IV contrast is eliminated renally, and its excretion into the urinary bladder can confuse the origin of contrast found in the bladder. The use of IV contrast also reduces the distinction between the fistula tract and the surrounding inflamed tissue. To better image an underlying disease process, it is reasonable to obtain a second phase with IV contrast.

Findings on CT scan that are suggestive of a CVF include:

- Oral or rectal contrast in the bladder on a non-IV contrast scan
- Air in the bladder with no prior instrumentation
- Presence of colonic diverticula
- Presence of abutting colon and bladder wall thickening

Besides confirming the presence of a fistula, the result of a CT scan can also be used to:

- Determine the etiology of the fistula (eg, findings of diverticular disease, cancer)
- Delineate the course of the fistulous tract, especially its relationship to the bladder trigone
- Assess adjacent anatomical structures in preparation for surgical management (eg, tumors or associated abscesses in the pelvis)

Lower gastrointestinal endoscopy to identify etiology — Patients in whom a CVF on CT is confirmed should then undergo a colonoscopy to determine the underlying etiology of the fistula.

CVFs are infrequently detected by lower gastrointestinal endoscopy. The reported sensitivities ranged between 0 and 55 percent, with most series reporting at the lower end of this range [1,2,32]. Thus, colonoscopy or flexible sigmoidoscopy should be used to diagnose the underlying etiology of a CVF rather than to identify the fistula itself. Endoscopy is the best test for assessing the colonic mucosa

and remains the most sensitive diagnostic test for colonic carcinoma [12]. If a suspicious lesion is found, biopsies can be taken to help guide management.

Cystoscopy for suspected malignant fistula — When patients are suspected of having a malignant CVF, a cystoscopy should be performed to rule out bladder involvement.

The sensitivity for detecting CVF on cystoscopy is between 40 and 87 percent [1,3,12]. Findings are usually nonspecific and include edema, erythema, and ulceration [13]. Thus, a cystoscopy should only be performed in patients whose CVF is suspected to be caused by cancer (bladder or colon) and knowledge of invasion would change management.

A fistula caused by colon cancer is typically confirmed by a lower gastrointestinal endoscopy. Bladder cancer is a rare cause of CVF (2 to 5 percent) [2,29,33], and should be suspected in the following patients:

- Patients with a personal history of bladder cancer
- Patients with frank hematuria
- Patients with evidence of a bladder mass on imaging
- Patients in whom workup (CT, endoscopy) fails to reveal a colonic cause of the CVF

In CVF patients who need a cystoscopy, one is often performed at the beginning of the fistula surgery and has the added benefit of facilitating ureteric stenting, a procedure often used to facilitate identification of the ureters in a challenging surgical field.

Infrequently performed tests — Other tests that are not routinely used in the diagnosis of CVF include [2,12,34]:

- Poppy seed test – The poppy seed test involves oral intake of 35 to 250 g of poppy seeds in a patient suspected of having a CVF [35,36]. Since the seeds pass through the gastrointestinal tract largely undigested, their presence in urine within 48 hours of consumption confirms the presence of a fistula. The test is easy and inexpensive to perform. Several authors have reported detection rates of 100 percent [35,36]. However, it provides no details regarding the location or etiology of the CVF. Thus, in patients who have a positive poppy seed test, a CT scan is still required.

- Plain radiography – A plain abdominal radiograph is not generally helpful. On occasion, an erect plain film can show an air-fluid level within the bladder in a patient with a CVF.

- Lower gastrointestinal exam (barium enema) – Barium enema (BE) has a low sensitivity for detecting CVF (approximately 30 percent) [2]. Radiographing a centrifuged first urine sample obtained after a BE (Bourne test) can increase the sensitivity to 90 percent [37]. Although the

ability to simultaneously detect a CVF and determine its underlying cause (eg, diverticulitis, colon cancer) is an advantage of BE [1], contrast-enhanced CT scans and lower gastrointestinal endoscopies have largely replaced BE in the diagnosis of CVF [2,3,12].

- Magnetic resonance imaging (MRI) – The efficacy of MRI has been established in the diagnosis of complex Crohn's fistulas and perianal fistulas with high sensitivities and specificities [12,34]. Its role in patients with confirmed or suspected CVF is still evolving. MRI has the advantage of being able to confirm the presence of a CVF, delineate its course, and assess the surrounding anatomy simultaneously without the use of oral or rectal contrast. The cost and accessibility of MRI, however, continue to limit its use to complex fistulas [12].

TREATMENT

The treatment of a colovesical fistula (CVF) is primarily surgical. Prior to surgery, however, patients need to be treated for any urologic or abdominal sepsis that may result from the CVF.

Treat symptomatic infection if present — Whenever a patient presents with urological or abdominal sepsis from a fistula, the treatment of sepsis always takes precedence over repair of the fistula. The initial treatment of urologic or abdominal sepsis includes fluid resuscitation, antibiotics, and control of the septic source. (See "Evaluation and management of suspected sepsis and septic shock in adults".)

The initial choice of antibiotic therapy should be directed toward covering colonic flora. A quinolone with metronidazole or amoxicillin-clavulanate is commonly used. In patients who develop sepsis from a CVF, the urinary bladder should be decompressed with a Foley catheter. The addition of bowel rest and total parenteral nutrition is optional [2] but generally not required in the treatment of CVF.

Definitive treatment of fistula — Once sepsis is resolved, most patients should undergo definitive repair of their CVFs. A defunctioning colostomy was once advocated as a simple means to allow the fistula to close spontaneously and prevent urinary sepsis [38], but the fistula closure rate was low, the risk of urinary tract infection persisted, and many CVFs recurred [1,2]. Thus, defunctioning colostomy is rarely performed alone. (See 'Operative management' below.)

Nonoperative management is reserved for patients who either have comorbidities that preclude surgery, unresectable cancer, or who have minimal symptoms and do not desire surgery. (See 'Nonoperative management' below.)

Operative management — Operative management of a colovesical fistula is guided by its underlying etiology. If there is ambiguity about whether a fistula is benign or malignant, it is best to treat it as if it were a malignant fistula. The extent of the resection is dictated by the fistula's etiology,

its location, and the condition of the patient. Patients generally do well with surgical management of CVFs, and postoperative recurrence is uncommon.

Benign fistula — Most CVFs are benign. A single-stage bowel resection with primary anastomosis, without diversion, is suitable for treating the great majority of such patients. Multistaged procedures are generally reserved for patients who are at a high risk of developing anastomotic leak or cannot tolerate a prolonged operation. For patients with a CVF caused by diverticulitis, laparoscopic treatment is feasible in experienced hands [39,40].

Preoperatively, all patients should have a urinary catheter inserted and positioned so that it can be accessed during the operation. In the initial approach, it is generally best to mobilize the colon proximally and distally to the fistula. Special attention must be paid to locate and preserve the left ureter.

In treating nonmalignant CVFs, the colon can often be dissected off the bladder using blunt dissection (the "pinch" technique). Where sharp dissection is necessary, caution must again be exercised to avoid injuring the ureter. Once separated, the fistulous tract itself may not be convincingly seen on either the bladder or the colon. If necessary, the fistula may be located by distending the bladder with methylene blue solution instilled through the urinary catheter [39]. The bladder side of the fistulous tract often does not require any intervention beyond decompression with Foley catheter. If the fistula opening is visible, it can be managed by simple closure with absorbable suture [39,41]. Partial cystectomy is not generally necessary since inflammation of the bladder is secondary to pathology in the colon and induration should resolve after the bowel has been resected. Where possible, we place the omentum between the colon and the bladder [42].

In patients with complex inflammatory bowel disease, small bowel and other structures may be involved in fistula formation, which may necessitate resection of multiple loops of bowel. (See "Operative management of Crohn disease of the small bowel, colon, and rectum", section on 'Fistula'.)

Multistage operation — Staged procedures are generally reserved for patients who are at a high risk of developing anastomotic leak or who cannot tolerate a prolonged operation. Risk factors for developing anastomotic leaks include gross fecal contamination, large abscesses, corticosteroid use, previous pelvic radiation therapy, and hemodynamic instability.

Options of multistage procedures include:

- Colonic resection and anastomosis with a protective ostomy, followed by closure of the ostomy (two-stage).

- Colonic resection with end colostomy, followed by colonic anastomosis with colostomy reversal (two-stage).

- Colonic resection with end colostomy, followed by colonic anastomosis with a protective ostomy, followed by closure of the ostomy (three-stage).

Laparoscopic operation — Although CVF was once considered a contraindication to laparoscopic resection [43], CVFs caused by diverticular disease are increasingly treated by experienced surgeons using laparoscopic techniques [44]. Compared with laparoscopic surgery for uncomplicated diverticulitis, laparoscopic treatment of CVFs requires a longer operative time and has a higher conversion rate (up to 30 percent) [39,40,45-48].

Although no series have been large enough to offer strong evidence for the advantages of laparoscopic surgery in the management of CVFs specifically, a meta-analysis of laparoscopic versus open surgery for sigmoid diverticulitis showed a significantly shorter hospital length of stay, decreased surgical site infections, and earlier return of bowel function [49].

Malignant fistula — Patients with a malignant CVF require a multivisceral resection of at least the affected portions of the colon and bladder. Principles of oncologic resection for the underlying cancer must be respected. For colon cancer, which is the most common malignancy causing CVF, this entails performing an en bloc resection of the cancer to negative proximal, distal, and radial margins, and a regional lymphadenectomy. (See "Surgical resection of primary colon cancer", section on 'General principles'.)

Depending upon the patient's condition, a single- or multistage procedure may be required to treat a malignant fistula. (See 'Multistage operation' above.)

Postoperative management of the bladder — We prefer to leave the urinary catheter in for seven days in most patients after a CVF repair. A postoperative cystogram at the time of Foley catheter removal is generally unnecessary in simple cases but can be performed at the surgeon's discretion or in cases involving complex bladder repair [39].

Traditionally, a urinary catheter was left indwelling for at least 10 days after a CVF repair to decompress the bladder and decrease the risk of urine leak [50-52]. Long periods of catheterization, however, are associated with increased risk of infection, discomfort, bladder atony, and prolonged hospitalization [52]. Other studies suggest that, in simple cases of CVF, removal of the catheter after seven days is safe and does not lead to more complications [41,52].

Nonoperative management — In CVF patients who do not desire surgery because their symptoms are minimal, expectant management is reasonable, provided that the fistula is not malignant. It used to be believed that foregoing operative repair may predispose patients to urosepsis or uremia, with up

to 75 percent dying from septic complications [1]. Contemporary studies, however, report much lower complication rates, with some fistulas even closing spontaneously [6,27,53,54].

In the setting of benign CVFs, some authors have reported the use of endoscopic injection of fibrin glue [55,56] or endoscopic clipping devices [57]. These techniques remain experimental with very few reported cases. Similarly, covered stents have been used in the palliation of patients with malignant and nonmalignant colovesical fistulas where surgery has been deemed inappropriate [58].

In patients who have both a malignant bowel stricture and a CVF, inserting a covered intestinal stent is a reasonable approach to managing both the stricture and the fistula. This potential benefit must be weighed against the known complications of enteral stenting [59]. (See "Enteral stents for the management of malignant colorectal obstruction".)

SUMMARY AND RECOMMENDATIONS

- A colovesical fistula (CVF) is an abnormal connection between the colon and urinary bladder. It is most commonly a complication of diverticulitis, cancer, or Crohn's disease. Men and older patients are affected more by CVFs. (See 'Introduction' above and 'Epidemiology' above and 'Etiology' above.)
- Patients generally present with lower urinary tract symptoms and signs, among which pneumaturia and fecaluria are virtually pathognomonic for CVFs. (See 'Clinical manifestations' above.)
- CVF should be suspected in patients who present with pneumaturia or fecaluria. The diagnosis is confirmed by abdominopelvic computed tomography (CT) scan with oral or rectal, but not intravenous, contrast demonstrating air or contrast material in the bladder with adjacent thickened colonic and vesicular walls. (See 'Evaluation and diagnosis' above.)
- Patients who are diagnosed with a CVF should undergo colonoscopy to rule out an underlying malignancy. Patients who are suspected of having a malignant fistula (due to colon or bladder cancer) should also undergo a cystoscopy to assess possible bladder involvement. (See 'Evaluation and diagnosis' above.)
- The treatment of a CVF is primarily surgical. Prior to surgery, however, patients need to be treated for any urologic or abdominal sepsis that may result from the CVF. (See 'Treatment' above.)
- For most patients with benign CVFs, a single-stage colonic resection followed by seven days of bladder drainage offers good results for a CVF repair. Patients who have a malignant fistula

require multivisceral resection following oncologic principles. (See 'Treatment' above.)

- Multistage procedures or nonoperative management could be used to treat CVFs in patients with comorbid conditions. (See 'Treatment' above.)

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Topic 104293 Version 5.0

Contributor Disclosures

Matt Strickland, MD, MBA, FRCSC Nothing to disclose **Marcus Burnstein, MD, MSc, FRCSC** Nothing to disclose **Zane Cohen, MD, FRCSC** Nothing to disclose **Martin Weiser, MD** Grant/Research/Clinical Trial Support: Clinical Genomics [Colorectal cancer (ctDNA)]. **Wenliang Chen, MD, PhD** Nothing to disclose

Contributor disclosures are reviewed for conflicts of interest by the editorial group. When found, these are addressed by vetting through a multi-level review process, and through requirements for references to be provided to support the content. Appropriately referenced content is required of all authors and must conform to UpToDate standards of evidence.

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